

Attorney Docket No. MSU 4.1-672
Appl. No. 10/725,214
Amdt. dated: June 27, 2006
Reply to Office Action of April 27, 2006

REMARKS/ARGUMENTS

Claims 1 and 5-7 are pending in the application. Claims 1 and 5-7 were rejected. Claims 6 and 7 are currently amended.

Claim Rejections- 35 U.S.C. §112

(1). Claims 1 and 5-7 were rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for an *in vitro* method for inhibiting the proliferation of colon cancer cells and stomach cancer cells, does not reasonably provide enablement for a method for *in vivo* inhibition in a mammal.

Enclosed is a Declaration under 37 C.F.R. §1.132 that shows that the cell lines HCT-116 and AGS are recognized as correlating to the specific conditions of human colon cancer and human stomach cancer, respectively. According to MPEP §2164.02, the issue of "correlation" is related to the issue of the presence or absence of working examples. "Correlation"

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refers to the relationship between *in vitro* or *in vivo* animal model assays and a disclosed or a claimed method of use. An *in vitro* or *in vivo* animal model example in the specification, in effect, constitutes a "working example" if that example "correlates" with a disclosed or claimed method invention. If the art is such that a particular model is recognized as correlating to a specific condition, then it should be accepted as correlating unless the examiner has evidence that the model does not correlate. Even with such evidence, the examiner must weigh the evidence for and against correlation and decide whether one skilled in the art would accept the model as reasonably correlating to the condition. *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (reversing the PTO decision based on finding that *in vitro* data did not support *in vivo* applications).

Since the initial burden is on the examiner to give reasons for the lack of enablement, the examiner must also give reasons for a conclusion of

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lack of correlation for an *in vitro* or *in vivo* animal model example. A rigorous or an invariable exact correlation is not required. *Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 USPQ 739, 747 (Fed. Cir. 1985). Given that the particular cell lines taught in the Examples are recognized as models correlating to the specific conditions of the claimed methods, it is believed that the specification provides enablement for the claimed methods for *in vivo* inhibition in a mammal. Reconsideration of the rejection is requested.

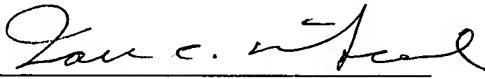
(2). Claims 6 and 7 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 6 and 7 have been amended to be dependent from the "method of Claim 1", so as to correct for the insufficient antecedent basis. Reconsideration of the rejection is requested.

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The Declaration under 37 C.F.R. §1.132 was submitted and the amendments were made to overcome the 35 U.S.C. §112 rejections set forth in the prior Office action. It is believed that the claims as amended present the rejected claims in better form for consideration on appeal. Entry of the amendments and the Declaration for purposes of appeal is requested.

Respectfully,



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Enclosure: Declaration under 37 C.F.R. §1.132.